UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND RELEVANT PRODUCTS LIABILITY LITIGATION	:	3:09-md-02100-DRH-PMF MDL No. 2100
DEBRA PORUPSKY and TYNESHA ROSS, Plaintiffs	:	Judge David R. Herndon COMPLAINT AND JURY DEMAND
vs. BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER SCHERING PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG, Defendants.	:	Civil Action No.: 3:11-cv-10011-DRH-PMF

Plaintiffs, by their attorneys, Burg Simpson Eldredge Hersh & Jardine, P.C., on behalf of themselves individually, upon information and belief, at all times hereinafter mentioned, allege as follows:

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to each of the Plaintiffs exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiffs reside.

2. Plaintiffs are filing this Complaint as permitted by Case Management Order #9 issued by Judge David R. Herndon of this Court. Plaintiffs state that but for that Order

permitting direct filing into the Southern District of Illinois, Plaintiffs would have filed in the United States District Court for the Northern District of California. Therefore, Plaintiffs respectfully request that at the time of transfer of this action back to the trial court for further proceedings this case be transferred to the Northern District of California as set forth in Case Management Order #9.

3. This Court has personal jurisdiction over Defendants consistent with the United States Constitution and MDL No. 2100 as Plaintiffs' claims arise out of Defendants' transaction of business and the commission of tortious acts within the State of California, and by virtue of Defendants' substantial, continuous and systematic contacts with the State of California and the State of Illinois unrelated to Plaintiffs' claims.

PARTY PLAINTIFF DEBRA PORUPSKY

4. Plaintiff, Debra Porupsky, is a citizen of the United States of America, and is a resident of Alameda County, California.

5. Plaintiff, Debra Porupsky, first began using Yaz in or around December 2008 and stopped using Yaz in or around February 2009.

6. As result of using Defendants' Yaz, Plaintiff Debra Porupsky, was caused to suffer a myocardial infarction in or about February 2009, and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.

7. The injuries and damages sustained by Plaintiff, Debra Porupsky, were caused by Defendants' Yaz.

PARTY PLAINTIFF TYNESHA ROSS

8. Plaintiff, Tynesha Ross, is a citizen of the United States of America, and is a resident of Alameda County, California.

9. Plaintiff, Tynesha Ross, first began using Yasmin in or around February 2009 and stopped using Yasmin in or around May 2009.

10. As result of using Defendants' Yasmin, Plaintiff Tynesha Ross, was caused to suffer a deep vein thrombosis in or about May 2009, and was caused to sustain severe and permanent personal injuries, pain, suffering, and emotional distress.

11. The injuries and damages sustained by Plaintiff, Tynesha Ross, were caused by Defendants' Yasmin.

PARTY DEFENDANTS

12. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is, and at all relevant times was, a corporation organized under the laws of the State of Delaware, with its principal place of business in the State of New Jersey.

13. Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. was formerly known as Berlex Laboratories, Inc., which was formerly known as Berlex, Inc. and BAYER HEALTHCARE PHARMACEUTICALS, INC. is the same corporate entity as Berlex, Inc. and Berlex Laboratories, Inc.

14. Upon information and belief, at all relevant times Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. has transacted and conducted business in the State of Illinois and in the State of California, and derived substantial revenue from interstate commerce.

15. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. expected or should have expected that its acts would have consequences within the United States of America, in the State of California, and in the State of Illinois, and derived substantial revenue from interstate commerce.

16. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. is the holder of approved New Drug Application No. 21-676 for YAZ.

17. Upon information and belief, Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. markets YAZ and Yasmin in the United States.

18. Upon information and belief, Defendant BAYER SCHERING PHARMA AG is a pharmaceutical company domiciled in Germany.

19. Defendant BAYER SCHERING PHARMA AG is formerly known as Schering AG and is the same corporate entity as Schering AG.

20. Upon information and belief, Schering AG was renamed BAYER SCHERING PHARMA AG effective December 29, 2006.

21. Upon information and belief, Defendant BAYER SCHERING PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive, Yasmin.

22. Upon information and belief, Defendant BAYER SCHERING PHARMA AG is the current owner of the patent(s) relating to the oral contraceptive, YAZ.

23. Defendant BAYER SCHERING PHARMA AG manufactures drospirenone and ethinyl estradiol, the progestin and estrogen contained in YAZ, Yasmin and Ocella.

24. Upon information and belief, Defendant BAYER SCHERING PHARMA AG has transacted and conducted business in the State of Illinois and in the State of California, and derived substantial revenue from interstate commerce.

25. Upon information and belief, Defendant BAYER SCHERING PHARMA AG expected or should have expected that its acts would have consequences within the United States of America, in the State of California, and in the State of Illinois, and derived substantial revenue from interstate commerce.

26. Upon information and belief, and at all relevant times Defendant BAYER SCHERING PHARMA AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute YAZ/Yasmin for use as a combination oral contraceptive.

27. Upon information and belief, Defendant BAYER CORPORATION is an Indiana corporation with its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

28. Upon information and belief, Defendant BAYER CORPORATION is the sole member of BAYER HEALTHCARE LLC, which owns 100% of Schering Berlin, Inc., which owns 100% of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC. As such, Defendant BAYER CORPORATION is a parent of Defendant BAYER HEALTHCARE PHARMACEUTICALS, INC.

29. At relevant times, Defendant BAYER CORPORATION was engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Yaz/Yasmin.

30. At relevant times, Defendant BAYER CORPORATION conducted regular and sustained business in the State of Illinois and in the State of California, by selling and distributing its products in the State of Illinois and engaged in substantial commerce and business activity in the State of Illinois and in the State of California.

31. Upon information and belief, Defendant BAYER HEALTHCARE LLC is a limited liability company duly formed and existing under and by the virtue of the laws of the State of Delaware, with its principal place of business located in the State of New York.

32. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC has transacted and conducted business in the State of Illinois and in the State of California, and derived substantial revenue from interstate commerce. Defendant BAYER CORPORATION is the sole member of Defendant BAYER HEALTHCARE LLC and as such, for purposes of establishing diversity of citizenship, Defendant BAYER HEALTHCARE LLC is a citizen of Indiana and Pennsylvania.

33. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC expected or should have expected that its acts would have consequences within the United States of America, in the State of Illinois, and in the State of California, and derived substantial revenue from interstate commerce.

34. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE LLC was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute YAZ/Yasmin for use as a combination oral contraceptive.

35. Upon information and belief, Defendant BAYER HEALTHCARE AG is a company domiciled in Germany and is the parent/holding company of Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC, and BAYER SCHERING PHARMA AG.

36. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG has transacted and conducted business in the State of Illinois and in the State of California, and derived substantial revenue from interstate commerce.

37. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG expected or should have expected that its acts would have consequences

within the United States of America, in the State of Illinois, and in the State of California, and derived substantial revenue from interstate commerce.

38. Upon information and belief, at all relevant times, Defendant BAYER HEALTHCARE AG exercises dominion and control over Defendants BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE PHARMACEUTICALS, INC., and BAYER SCHERING PHARMA AG.

39. Upon information and belief, Defendant BAYER AG is a German chemical and pharmaceutical company that is headquartered in Leverkusen, North Rhine-Westphalia, Germany.

40. Upon information and belief, Defendant BAYER AG is the third largest pharmaceutical company in the world.

41. Upon information and belief, and at all relevant times Defendant BAYER AG is the parent/holding company of all other named Defendants.

42. Upon information and belief, at all relevant times, Defendant BAYER AG has transacted and conducted business in the State of Illinois and in the State of California, and derived substantial revenue from interstate commerce.

43. Upon information and belief, at all relevant times, Defendant BAYER AG expected or should have expected that its acts would have consequences within the United States of America, in the State of California, and in the State of Illinois, and derived substantial revenue from interstate commerce.

44. Upon information and belief, at all relevant times, Defendant BAYER AG was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute YAZ/Yasmin for use as a combination oral contraceptive.

45. Defendants, BAYER HEALTCHCARE PHARMACEUTICALS, INC., BAYER SCHERING PHARMA AG, BAYER CORPORATION, BAYER HEALTHCARE LLC, BAYER HEALTHCARE AG, and BAYER AG shall, hereinafter, be collectively referred to as "Bayer" or "Defendants."

NATURE OF THE CASE

Bayer's Combined Oral Contraceptives – Yasmin and Yaz

46. Yasmin and Yaz are birth control pills manufactured and marketed by Bayer. They are combination oral contraceptives, or "COCs," meaning that they contain an estrogen component and a progestin component. Together, these steroidal components work together in COCs to suppress ovulation, fertilization, and implantation and thus prevent pregnancy.

47. Yasmin and Yaz were approved by the Food and Drug Administration for marketing in 2001 and 2006 respectively.

Yasmin and Yaz Contain a "Fourth Generation" Progestin

48. The estrogen component in Yasmin and Yaz is known generically as ethinyl estradiol. The progestin component is known as drospirenone. Yasmin contains 0.03 milligrams of ethinyl estradiol, and Yaz contains 0.02 milligrams of ethinyl estradiol. Both products contain 3 milligrams of drospirenone.

49. Yasmin and Yaz are different from other combined hormonal birth control pills in that they contain drospirenone, a progestin that is unlike other progestins available in the United States and was never before marketed in the United States prior to its use in Yasmin.

50. Shortly after the introduction of combined oral contraceptives in the 1960's, doctors and researchers found that women using birth control pills had a higher risk of blood clots, heart attacks, and strokes than women not using the pill. As a result, the various brands of

birth control pills were reformulated to reduce the amounts of estrogen. As the amounts of estrogen levels reduced, so too did the risk of blood clots, heart attacks, and strokes.

51. During this time, new progestins were being developed, which became known as "second generation" progestins (e.g. lovenorgestrel). These second generation progestins, when combined with the lower amounts of the estrogen, ethinyl estradiol, helped to reduce the risk of blood clots, heart attacks, and strokes and were considered safer for women.

52. During the 1990's, new "third generation" progestins were developed. Unfortunately, these "third generation" progestins (e.g. gestodene and desogestrel) have been associated with a greater risk of blood clots in the deep veins (deep vein thrombosis or "DVT") and lungs (pulmonary embolism or "PE"). As a result of this increased risk of blood clots, the FDA has required that products containing third generation progestins include a Warning of the potentially increased risk of thrombosis.

53. Yasmin and Yaz contain the same estrogen component, ethinyl estradiol, that has been used in the lower dose birth control pills for decades.

54. However, drospirenone is a new type of progestin and is considered a "fourth generation" progestin. No other birth control pills contain drospirenone, except for a recently approved generic version of Yasmin and Yaz marketed under the trade name Ocella.

55. Since drospirenone is new, there are not decades of data available to support its safe use as there are with second generation progestins. Studies that were done prior to FDA approval, however, indicate that drospirenone has certain effects that are different from those of traditional second generation progestins, and potentially more dangerous.

56. One possible mechanism of action is that drospirenone interacts differently with ethinyl estradiol compared to other progestins, such that it does not sufficiently counterbalance

the clotting effects of estrogen as do other progestins, particularly the second generation progestins.

57. Another possible mechanism of action is that drospirenone causes an increase in potassium levels in the blood, which can lead to a condition known as hyperkalemia if the potassium levels become too high.

58. Hyperkalemia can cause heart rhythm disturbances, such as extrasystolies, pauses, or bradycardia. If left untreated, hyperkalemia can be fatal.

59. If hyperkalemia disrupts the normal heart rhythms, the flow of blood through the heart can be slowed to the point that it permits blood clots to form. Blood clots in the heart can then lead to heart attacks, or the clots can break off and travel to the lungs where they can cause pulmonary embolism, or can travel to the brain causing stroke.

60. Indeed, during the brief time that Yasmin and Yaz have been sold in the United States, hundreds of reports of injury and death have been submitted to the FDA in association with Defendants' products.

61. In April 2002, the British Medical Journal reported that the Dutch College of General Practitioners recommended that older second generation birth control pills be prescribed in lieu of Yasmin as a result of 40 cases of venous thrombosis among women taking Yasmin.

62. In February 2003, a paper entitled *Thromboembolism Associated With the New Contraceptive Yasmin* was published in the British Medical Journal detailing a Netherlands Pharmacovigilance Centre report of five additional reports of thromboembolism where Yasmin was suspected as the cause, including two deaths.

63. In fact, in less than a five-year period, from the first quarter of 2004 through the third quarter of 2008, over 50 reports of death among users of Yasmin and Yaz have been filed with the FDA.

64. These reports include deaths associated with cardiac arrhythmia, cardiac arrest, intracardiac thrombus, pulmonary embolism, and stroke in women in their child bearing years.

65. Some deaths reported occurred in women as young as 17 years old.

66. Significantly, reports of elevated potassium levels are frequently included among the symptoms of those suffering death while using Yasmin or Yaz.

Over-Promotion of Yasmin and Yaz

67. Defendants market Yasmin and Yaz as providing the same efficacy as other birth control pills in preventing pregnancy, but with additional benefits.

68. However, because Yasmin and Yaz contain the fourth generation progestin drospirenone, they present additional health risks not associated with other birth control pills.

69. For example, prior to its integration with Defendant Bayer in 2006, Berlex Laboratories promoted Yasmin's fourth generation progestin, drospirenone, by stating, "Ask about Yasmin, and the difference a little chemistry can make."

70. In response, on July 10, 2003, the FDA objected to the characterization that drospirenone was a benefit compared to the progestin used in other combined oral contraceptives and issued a warning letter stating, "FDA is not aware of substantial evidence of substantial clinical experience demonstrating that Yasmin is superior to other COCs or that the drospirenone in Yasmin is clinically beneficial. On the contrary, FDA is aware of the added clinical risks associated with drospirenone [.]"

71. The FDA's warning letter continued by stating that the advertisement failed "to communicate that the potential to increase potassium is a risk" or that "increased serum potassium can be dangerous."

72. More recently, Defendants advertised that its product Yaz was indicated for treatment of premenstrual syndrome or "PMS," as opposed to the more serious condition of premenstrual dysphoric disorder or "PMDD."

73. Defendants also advertised that Yaz contained the added benefit of preventing or reducing acne.

74. In response, on October 3, 2008, the FDA issued another warning letter to Defendant Bayer for the misleading advertisement, reiterating that the marketing was misleading because it promoted Yaz for medical conditions beyond the limits of the FDA approval, and adding that "Yaz has additional risks because it contains the progestin, drospirenone … which can lead to hyperkalemia in high risk patients, which may result in potentially serious heart and health problems."

75. The FDA further warned in its October 3, 2008 letter that Yaz "does not result in completely clear skin" and that Defendants' "TV Ads misleadingly overstate the efficacy of the drug."

76. Indeed, the FDA felt Defendants' overpromotion of Yasmin was so severe that it required Bayer to run new TV advertisements to correct the previous misleading Yaz advertisements regarding acne and premenstrual syndrome.

77. Bayer ultimately agreed to spend at least $20 million on corrective TV advertisements and to submit all Yaz advertisements to the FDA for advanced screening for the next six years.

Plaintiff Debra Porupsky's Use of Yaz and Resulting Injuries

78. As a result of Defendants' claim regarding the effectiveness and safety of Yaz, Plaintiff Debra Porupsky's medical provider prescribed and Debra Porupsky began using Yaz in

or around December 2008. Plaintiff Debra Porupsky continued using Yaz until February 2009. In February 2009, Plaintiff Debra Porupsky was diagnosed with a myocardial infarction.

79. As a direct and proximate result of using Yaz, Plaintiff Debra Porupsky suffered the injuries described above.

80. Prior to Plaintiff's use of Yaz, Defendants knew or should have known that use of Yaz created a higher risk of serious personal injury than other oral contraceptives on the market, including but not limited to second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.

81. Therefore, at the time Plaintiff used Yaz, Defendants knew or should have known that the use of Yaz created an increased risk to consumers of serious personal injury, including deep vein thrombosis, pulmonary embolism, heart attacks, stroke, and even death.

82. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yaz, Defendants failed to adequately warn Plaintiff Debra Porupsky and/or her health care providers of said serious risks before she used the products.

83. Had Plaintiff Debra Porupsky and/or her heath care providers known of the increased risks and dangers associated with Yaz, she would not have used the product and would not have suffered a myocardial infarction in February of 2009.

84. As a direct and proximate result of her use of Yaz, Plaintiff Debra Porupsky has suffered significant harm, conscious pain and suffering, physical injury and bodily impairment, including, but not limited to, suffering from a myocardial infarction, which may have caused permanent effects, and which may continue in the future to cause her physical effects and damage which will affect her throughout her lifetime.

85. Further, as a direct and proximate result of her use of Yaz, Plaintiff Debra Porupsky has suffered significant mental anguish and emotional distress and will continue to

suffer physical limitations, pain, injury, damages, harm, and mental and emotional distress in the future.

86. Plaintiff Debra Porupsky has also incurred medical expenses and other economic harm and will continue to incur such expenses in the future, as a direct and proximate result of her use of Yaz.

Plaintiff Tynesha Ross's Use of Yasmin and Resulting Injuries

87. As a result of Defendants' claim regarding the effectiveness and safety of Yasmin, Plaintiff Tynesha Ross's medical provider prescribed and Tynesha Ross began using Yasmin in or around February 2009. Plaintiff Tynesha Ross continued using Yasmin until May 2009. In May 2009, Plaintiff Tynesha Ross was diagnosed with a deep vein thrombosis.

88. In December 2009, Plaintiff Tynesha Ross suffered a miscarriage.

89. As a direct and proximate result of using Yasmin, Plaintiff Tynesha Ross suffered the injuries described above.

90. Prior to Plaintiff's use of Yasmin, Defendants knew or should have known that use of Yasmin created a higher risk of serious personal injury than other oral contraceptives on the market, including but not limited to second generation oral contraceptives, and that, when taken as directed, such use was unreasonably dangerous to consumers.

91. Therefore, at the time Plaintiff used Yasmin, Defendants knew or should have known that the use of Yasmin created an increased risk to consumers of serious personal injury, including deep vein thrombosis, pulmonary embolism, heart attacks, stroke, and even death.

92. Despite the fact that Defendants knew or should have known of the serious health risks associated with the use of Yasmin, Defendants failed to adequately warn Plaintiff Tynesha Ross and/or her health care providers of said serious risks before she used the products.

93. Had Plaintiff Tynesha Ross and/or her heath care providers known of the increased risks and dangers associated with Yasmin, she would not have used the product and would not have suffered a deep vein thrombosis in May of 2009.

94. As a direct and proximate result of her use of Yasmin, Plaintiff Tynesha Ross has suffered significant harm, conscious pain and suffering, physical injury and bodily impairment, including but not limited to, suffering from a deep vein thrombosis, which may have caused permanent effects, and which may continue in the future to cause her physical effects and damage which will affect her throughout her lifetime.

95. Further, as a direct and proximate result of her use of Yasmin, Plaintiff Tynesha Ross has suffered significant mental anguish and emotional distress and will continue to suffer physical limitations, pain, injury, damages, harm, and mental and emotional distress in the future.

96. Plaintiff Tynesha Ross has also incurred medical expenses and other economic harm and will continue to incur such expenses in the future, as a direct and proximate result of her use of Yasmin.

FIRST CAUSE OF ACTION

Strict Products Liability
Defective Manufacturing

97. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein at length.

98. Defendants were the manufacturers, designers, distributors, sellers, and/or suppliers of Yasmin and Yaz.

99. Defendants' Yasmin and Yaz were defective in their manufacture and construction when they left the hands of Defendants in that they deviated from design

specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications.

100. As a direct and proximate result of Plaintiffs Debra Porupsky and Tynesha Ross use of Yaz and Yasmin, as manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce by Defendants, as well as Defendants' failure to comply with federal requirements and standards, Plaintiffs Debra Porupsky and Tynesha Ross suffered harm, damages, and economic loss.

101. Defendants' actions and omissions as alleged in this Complaint constitute willful and deliberate oppression, fraud, wantonness, and/or malice with respect to Plaintiffs, so as to warrant the imposition of punitive damages.

SECOND CAUSE OF ACTION

Strict Products Liability
Defect in Design or Formulation

102. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein at length.

103. Defendants' Yasmin and Yaz, as manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce, were defective in design or formulation in that, when they left the hands of Defendants, the foreseeable risks of the products exceeded the benefits associated with their design or formulation.

104. The foreseeable risks associated with the design or formulation of Defendants' Yasmin and Yaz include, but are not limited to, the fact that the design or formulation of Defendants' Yasmin and Yaz was more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

105. As a direct and proximate result of Plaintiffs Debra Porupsky's and Tynesha Ross's use of Yaz and Yasmin, as manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce by Defendants, as well as Defendants' failure to comply with federal requirements and standards, Plaintiffs Debra Porupsky and Tynesha Ross suffered harm, damages, and economic loss.

106. Defendants' actions and omissions as alleged in this Complaint constitute willful and deliberate oppression, fraud, wantonness, and/or malice with respect to Plaintiffs, so as to warrant the imposition of punitive damages.

THIRD CAUSE OF ACTION

Strict Products Liability
Defect Due to Inadequate Warning

107. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein at length.

108. The Yasmin and Yaz manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce by Defendants were defective due to inadequate warning or instruction because the Defendants knew or should have known that the products were unreasonably dangerous by creating significant risks of serious bodily harm and death to consumers, including Plaintiffs Debra Porupsky and Tynesha Ross, and they failed to adequately warn consumers and/or their health care providers of such risks.

109. The Yasmin and Yaz manufactured, designed, sold, distributed, supplied, marketed, and/or placed in the stream of commerce by the Defendants were defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of serious bodily harm and death from the administration of Yasmin and Yaz,

Defendants failed to provide an adequate warning to consumers and/or their health care providers of the products, knowing the products could cause serious bodily harm and death.

110. As a direct and proximate result of these defective products, Plaintiffs Debra Porupsky and Tynesha Ross suffered harm, damages, and economic loss.

111. Defendants' actions and omissions as alleged in this Complaint constitute willful and deliberate oppression, fraud, wantonness, and/or malice with respect to Plaintiffs, so as to warrant the imposition of punitive damages.

FOURTH CAUSE OF ACTION

Strict Products Liability
Defect Due to Failure to Adequately Test

112. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

113. Defendants advised consumers and the medical community that Yasmin and Yaz contained the same safety profile as other oral hormonal birth control pills. However, Defendants failed to adequately test the safety of Yasmin and Yaz versus other oral hormonal birth control pills.

114. Had Defendants adequately tested the safety of Yasmin and Yaz versus other oral hormonal birth control pills and disclosed the results to the medical community or the public, Plaintiffs would not have used, and their physicians would not have prescribed, Yasmin and Yaz.

115. As a direct and proximate result of Defendants' failure to adequately test the safety of Yasmin and Yaz versus other oral hormonal birth control pills, Plaintiffs Debra Porupsky and Tynesha Ross suffered personal injury, economic and non-economic damages, and will continue to suffer such harm, damages, and economic loss in the future.

116. Defendants' conduct as alleged in this Complaint demonstrates that Defendants acted maliciously, wantonly, or with recklessness suggesting an improper motive so as to warrant the imposition of punitive damages.

FIFTH CAUSE OF ACTION

Negligence

117. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein at length.

118. Defendants owed a duty to exercise reasonable care in the design, manufacture, testing, marketing, distributing, sale, and/or post-sale surveillance of Defendants' Yasmin and Yaz, including a duty to ensure that their products did not contain contaminants that posed a risk of bodily harm and adverse events, including death.

119. Defendants failed to exercise ordinary care in the design, formulation, manufacture, testing, quality assurance, quality control, distribution, marketing, sale, and/or post-sale surveillance of Defendants' Yasmin and Yaz in that Defendants knew or should have known that Defendants' Yasmin and Yaz could cause such significant bodily harm and death and were not safe for administration to consumers.

120. Despite the fact that Defendants knew or should have known that Defendants' Yasmin and Yaz posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market Defendants' Yasmin and Yaz for administration to patients.

121. Defendants knew or should have known that consumers such as Plaintiffs Debra Porupsky and Tynesha Ross would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above.

122. As a direct and proximate result of Defendants' negligence, Plaintiffs Debra Porupsky and Tynesha Ross suffered harm, damages, and economic loss.

123. Defendants' actions and omissions as alleged in this Complaint constitute willful and deliberate oppression, fraud, wantonness, and/or malice with respect to Plaintiffs, so as to warrant the imposition of punitive damages.

SIXTH CAUSE OF ACTION

Breach of Express Warranty

124. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein at length.

125. Defendants expressly warranted that Defendants' Yasmin and Yaz were of merchantable quality and safe for the use by consumers and users, including Plaintiffs Debra Porupsky and Tynesha Ross, for their intended purpose.

126. Defendants breached said express warranties in that Defendants' Yasmin and Yaz were not safe and fit for their intended use and, in fact, caused debilitating and lethal adverse effects.

127. As a direct and proximate result of Defendants' breach of warranty, Plaintiffs Debra Porupsky and Tynesha Ross suffered harm, damages, and economic loss.

SEVENTH CAUSE OF ACTION

Breach of Implied Warranty

128. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein at length.

129. At the time Defendants manufactured, marketed, sold, and distributed Yasmin and Yaz, Defendants knew of the use for which Defendants' Yasmin and Yaz were intended and impliedly warranted that Defendants' Yasmin and Yaz were of merchantable quality and safe for such use.

130. Plaintiffs Debra Porupsky and Tynesha Ross and their medical providers reasonably relied upon the skill, judgment and representations of Defendants as to whether Defendants' Yasmin and Yaz were of merchantable quality and safe for their intended use and upon Defendants' implied warranty as to such matters.

131. Contrary to the implied warranty, Defendants' Yasmin and Yaz were unsafe for their intended use and were not of merchantable quality because they were as unreasonably dangerous as described herein.

132. As a direct and proximate result of Defendants' breach of warranty, Plaintiffs Debra Porupsky and Tynesha Ross suffered harm, damages, and economic loss.

EIGHTH CAUSE OF ACTION

Fraudulent Misrepresentation

133. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein at length.

134. Defendants knowingly and intentionally made material and false and misleading representations to Plaintiffs Debra Porupsky and Tynesha Ross, her physicians and to the public that the Defendants' Yasmin and Yaz had been tested and was safe and effective.

135. Defendants' representations were in fact false, as the Defendants' Yasmin and Yaz had not been adequately tested and were not safe and effective.

136. Defendants knew, or should have known, that Yasmin and Yaz created an unreasonable risk of serious bodily injury or death to consumers.

137. These representations were made by Defendants with the intent of defrauding and deceiving the medical community, Plaintiffs Debra Porupsky and Tynesha Ross, and the public in general, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, dispense, and/or purchase the subject

products, all of which is evidence of callous, reckless and willful disregard for the health, safety and welfare of Plaintiffs Debra Porupsky and Tynesha Ross.

138. At the time said representations were made by Defendants, and at the time Plaintiffs Debra Porupsky and Tynesha Ross used the subject products, Plaintiff Debra Porupsky and Tynesha Ross and/or her medical providers were unaware of the falsity of said representations and reasonably believed them to be true.

139. In justifiable reliance upon said representations, Plaintiffs Debra Porupsky and Tynesha Ross and/or their medical providers were induced to and did use the subject products, thereby causing Plaintiffs Debra Porupsky and Tynesha Ross to suffer severe personal injuries.

140. As a direct and proximate result of Defendants' fraudulent concealment and misrepresentations, Plaintiffs Debra Porupsky and Tynesha Ross suffered harm, damages, and economic loss.

141. Defendants' actions and omissions as alleged in this Complaint constitute willful and deliberate oppression, fraud, wantonness, and/or malice with respect to Plaintiffs, so as to warrant the imposition of punitive damages.

NINTH CAUSE OF ACTION

Violation of Business and Professions Code § 17200

142. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

143. Plaintiffs bring this cause of action pursuant to California *Business & Professions Code* §17204, in Plaintiffs' individual capacities, and not on behalf of the general public.

144. California *Business & Professions Code* §17200 provides that unfair competition shall mean and include "all unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising."

145. The acts and practices described above were and are likely to mislead the general public and therefore constitute unfair business practices within the meaning of California *Business & Professions Code* §17200. The acts of untrue and misleading advertising are, by definition, violations of California *Business & Professions Code* §17200. This conduct includes, but is not limited to:

a. Representing to Plaintiffs, Plaintiffs' physicians, and the general public that Yasmin and Yaz were safe, fit, and effective for human use, knowing that said representations were false, and concealing from Plaintiffs, Plaintiffs' physicians, and the general public that Yasmin and Yaz had a serious propensity to cause injuries to users;

b. Engaging in advertising programs designed to create the image, impression and belief by consumers and physicians that Yasmin and Yaz were safe for human use, even though Defendants knew this to be false, and even though Defendants had no reasonable grounds to believe them to be true; and

c. Purposely downplaying and understating the health hazards and risks associated with Yasmin and Yaz.

146. These practices constitute unlawful, unfair and fraudulent business acts or practices, within the meaning of California *Business & Professions Code* §17200, as well as unfair, deceptive, untrue and misleading advertising as prohibited by California *Business & Professions Code* §17500.

147. The unlawful, unfair and fraudulent business practices of Defendants described above present a continuing threat to members of the public in that Defendants continue to engage in the conduct described therein.

148. As a result of their conduct described above, Defendants have been and will be unjustly enriched. Specifically, Defendants have been unjustly enriched by receipt of ill-gotten

gains from the sale of Yasmin and Yaz in California, sold in large part as a result of the acts and omissions described herein.

149. Because of fraudulent misrepresentations made by Defendants as detailed above, and the inherently unfair practice of committing a fraud against the public by intentionally misrepresenting and concealing material information, the acts of Defendants described herein constitute unfair or fraudulent business practices.

150. Plaintiffs, pursuant to California *Business & Professions Code* §17203, seek an order of this court compelling Defendants to provide restitution and injunctive relief calling for Defendants to cease unfair business practices in the future.

TENTH CAUSE OF ACTION

Violation of Business and Professions Code § 17500

151. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

152. Plaintiffs bring this cause of action pursuant to California *Business & Professions Code* §17500, in Plaintiffs' individual capacities and not on behalf of the general public.

153. California *Business & Professions Code* §17500 provides that it is unlawful for any person, firm, corporation, or association to dispose of property or perform services, or to induce the public to enter into any obligation relating thereto, through the use of untrue or misleading statements.

154. At all times herein alleged Defendants have committed acts of disseminating untrue and misleading statements as defined by California *Business & Professions Code* §17500 by engaging in the following acts and practices with intent to induce members of the public, including healthcare professionals, to purchase and use Yasmin and Yaz:

a. Representing to Plaintiffs, Plaintiffs' physicians, and the general public that Yasmin and Yaz were safe, fit, and effective for human use, knowing that said representations were false, and concealing from Plaintiffs, Plaintiffs' physicians, and the general public that Yasmin and Yaz had a serious propensity to cause injuries to users;

b. Engaging in advertising programs designed to create the image, impression and belief by consumers and physicians that Yasmin and Yaz were safe for human use, even though Defendants knew this to be false, and even though Defendants had no reasonable grounds to believe them to be true; and

c. Purposely downplaying and understating the health hazards and risks associated with Yasmin and Yaz.

155. The foregoing practices constitute false and misleading advertising within the meaning of California *Business & Professions Code* §17500.

156. The acts of untrue and misleading statements by Defendants described herein above present a continuing threat to members of the public in that the acts alleged herein are continuous and ongoing, and the public will continue to suffer the harm alleged herein.

157. As a result of their conduct described above, Defendants have been and will be unjustly enriched. Specifically, Defendants have been unjustly enriched by receipt of ill-gotten gains from the sale and prescription of Yasmin and Yaz in California, sold in large part as a result of the acts and omissions described herein.

158. California *Business & Professions Code* §17535, Plaintiff seeks an order of this court compelling the Defendants to provide restitution and injunctive relief calling for Defendants, and each of them, to cease unfair business practices in the future.

159. Plaintiffs seek restitution of the monies collected by Defendants and other injunctive relief to cease such false and misleading advertising in the future.

ELEVENTH CAUSE OF ACTION

Violation of Civil Code § 1750 *et seq.*

160. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

161. Plaintiffs are informed and believe and thereon allege that Defendants, by the acts and misconduct alleged herein, violated the Consumer Legal Remedies Act, California Civil Code §§ 1750 *et seq*. (the "CLRA").

162. Plaintiffs hereby seek injunctive relief as appropriate against Defendants for their violations of the CLRA. The CLRA applies to Defendants' actions and conduct described herein because it extends to transactions which are intended to result, or which have resulted, in the sale of goods to consumers.

163. Plaintiffs are "consumers" within the meaning of California Civil Code § 1761(d).

164. Defendants have violated, and continue to violate, the CLRA in representing that goods have characteristics and benefits which they do not have in violation of California Civil Code §§ 1770(a)(5).

165. At all times herein alleged Defendants have committed acts of disseminating untrue and misleading statements as defined by California Civil Code § 1770 by engaging in at least the following acts and practices with intent to induce members of the public, including healthcare providers, to purchase and use Yasmin and Yaz:

a. Representing to Plaintiff, Plaintiff's physicians, and the general public that Yasmin and Yaz were safe, fit, and effective for human use, knowing that said representations were false, and concealing from Plaintiffs, Plaintiffs' physicians, and the general public that Yasmin and Yaz had a serious propensity to cause injuries to users;

b. Engaging in advertising programs designed to create the image, impression and belief by consumers and physicians that Yasmin and Yaz were safe for human use, even though Defendants knew this to be false, and even though Defendants had no reasonable grounds to believe them to be true; and

c. Purposely downplaying and understating the health hazards and risks associated with Yasmin and Yaz.

166. The foregoing practices constitute false and misleading advertising and representations within the meaning of California Civil Code § 1770. The acts of untrue and misleading statements by Defendants described herein present a continuing threat to members of the public and individual consumers in that the acts alleged herein are continuous and ongoing, and the public and individual consumers will continue to suffer harm as alleged herein.

167. Unless Defendants are enjoined from continuing to engage in these violations of the CLRA, Plaintiffs and members of the general public will continue to be harmed by the wrongful actions and conduct of Defendants.

168. Pursuant to California Civil Code § 1780, Plaintiffs seek an order of this court for injunctive relief calling for Defendants, and each of them, to cease such deceptive business practices in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. For any other causes of action and/or claims as may be compensable under local laws and/or statutes as may apply under the laws in the jurisdiction and venue in which this case will be transferred for trial in accordance with Case Management Order #9 issued by United States District Court Judge David R. Herndon.

2. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiffs, health care costs, medical monitoring, together with interest and costs as provided by law;

3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

4. Awarding all applicable statutory damages of the state whose laws will govern this action;

5. Awarding Plaintiffs reasonable attorneys' fees;

6. Awarding Plaintiffs the costs of these proceedings; and

7. Such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand trial by jury as to all issues.

Dated: January 4, 2011

RESPECTFULLY SUBMITTED,

s/ Seth A. Katz

Seth A. Katz
Daniel E. McKenzie
BURG SIMPSON
ELDREDGE HERSH & JARDINE, P.C.
40 Inverness Drive East
Englewood, Colorado 80112
Tel: (303) 792-5595
Fax: (303) 708-0527
skatz@burgsimpson.com
dmckenzie@burgsimpson.com

Attorneys for Plaintiffs